Philadelphia Inquirer Posted on Sun, Jul. 19, 2009

By Marie McCullough and Josh Goldstein Inquirer Staff Writers

James Armstrong had no way to know that his prostate-cancer treatment had gone dangerously awry as he recovered from the brief procedure at the Philadelphia VA Medical Center in August 2007.

Doctors for the Vietnam War veteran from West Philadelphia, however, should have known, federal investigators concluded.

The dozens of tiny radioactive seeds they had implanted in Armstrong's prostate gland were delivering only about a quarter of the radiation called for in his treatment plan - too little by established standards to wipe out his cancer.

Armstrong's doctors, led by University of Pennsylvania radiation oncologist Gary Kao, didn't recognize their error because they hadn't done the crucial last step of the brachytherapy procedure - calculating the actual radiation dosage administered to their patient - investigators found.

For a year, starting in November 2006, the computer workstation with the software used to calculate the post-implant dosages was unplugged from the hospital's network.

All that time, no one took steps to plug it back in, work around it, or tell patient-safety officials, investigators found.

As a result, post-implant calculations weren't performed during that period for Armstrong and 15 other patients, according to the U.S. Nuclear Regulatory Commission, which oversees medical use of radiation.

Even after the computer was finally reconnected to the network, investigators discovered, post-implant calculations continued to be omitted for an additional seven patients.

"The standard of care is that you do post-implant dosimetry in every case.

There's never an excuse for not doing it," said radiation oncologist Gregory Merrick of Wheeling, W. Va., author of a textbook on brachytherapy. "Most institutions will not allow you to continue doing procedures if you have no quality assurance."

The unplugged computer was emblematic of the disconnection and disregard that investigators say pervaded the brachytherapy program at the Philadelphia VA.

Between February 2002, when the program opened, and June 2008, when it was shut down, 92 of 114 prostate-cancer patients received too little radiation or too much.

On Wednesday, a congressional panel will hold a hearing in Washington to question Kao and other key individuals from the VA, Penn and the NRC.

"The VA abdicated its responsibility . . . by allowing this program to operate without adequate safeguards or supervision," said U.S. Rep. John Adler (D., N.J.), who has pushed for a congressional investigation.

Viewed as essential

There are no laws or federal regulations requiring that radiation doses be calculated after a brachytherapy implant. However, professional radiology organizations say it is essential for good practice.

Tamara A. LaCouture, acting chief of radiation oncology at Cooper University Hospital in Camden, said an implant there would be canceled or postponed rather than go without post-implant dosimetry.

It is not surprising, then, that NRC and VA investigators spent considerable time delving into why the calculations weren't done for more than a year at the Philadelphia VA.

Their investigative reports blamed a "computer interface problem" - the same terminology Kao used during his testimony last month at a congressional hearing.

The implication was that some intractable technology breakdown was behind the lapse in care.

In fact, technology had little to do with the breakdown, as James Bagian discovered when he led an inquiry at the Philadelphia VA and the veterans' health system's 12 other brachytherapy programs.

Bagian, a Philadelphia-born physician and former astronaut who is now the national VA's patient-safety director, discovered that the "interface problem" was nothing more than the disconnected computer.

Here's what else his inquiry found:

The computer was initially unplugged so that another medical device could use the network port. Then, various departments dithered and ducked a request for an additional network port, which was finally installed - after a year.

Some doctors, physicists, and other professionals at the VA acknowledged it was "clinically inappropriate" to omit the post-implant calculations. Some said they had informed their "chain of command."

When asked why they didn't tell the hospital's patient-safety officer, they said "it had not occurred to them to do so."

VA spokesman Katie Roberts said that the department had shut down the Philadelphia program after the problem was discovered last spring and since that time had worked to inform and treat all the affected veterans.

"VA deeply regrets this unfortunate occurrence," Roberts said in a statement. "VA is actively using this experience to implement stricter protocols of accountability and transparency throughout the department."

Penn is cooperating fully with the various investigations into these cases, said Susan E. Phillips, senior vice president at the Penn health system.

And, she added, "we are continuing to work closely with the Philadelphia VA to provide veterans with the best possible medical care."

While the investigations and recriminations continue, brachytherapy experts worry that the Philadelphia program's problems may foster the incorrect perception that the treatment itself is inferior.

That, Merrick said, would be an even bigger shame than the flawed treatments.

"If this gets painted that it's a horrible procedure, we're not doing anybody any favors," he said. "Brachy is a remarkably good treatment for prostate cancer. The cure rates and quality of life of patients compare favorably to all other treatment modalities."

Many played key roles

Reviews by the VA and the NRC found that the brachytherapy program underdosed 57 veterans while 37 got excessive doses of radiation to nearby tissues.

Kao, who did almost all the errant procedures, is the only person officials have publicly identified. But many others - including medical physicists, urologists, and radiation technologists from Penn, and VA employees - played key roles in the program.

Penn, which trains young doctors at the hospital, contracts with the VA to provide a raft of medical services, including radiation oncology.

No one can say how many of the 92 veterans face a poor prognosis as a result of the treatment lapses, but for Armstrong, the damage is clear.

Like the other men who received inferior care, Armstrong learned of it last summer. Philadelphia VA officials asked the 62-year-old veteran come in for a new CAT scan that would be used to review the quality of his implant.

The VA's review showed that his prostate had received only 27 percent of the prescribed radiation dose. And it appeared that his bladder and bowel received excessive radiation from errantly placed seeds.

Armstrong suffers from severe pain during urination. He also has trouble controlling his bladder and bowels, and uses as many as five adult diapers each day.

Last October, the VA flew Armstrong - and seven other veterans with suspected treatment failures - to the Puget Sound VA in Seattle, an internationally recognized leader in brachytherapy. There, the men received corrective "touch-up" implants.

Armstrong's "original implant was grossly inadequate by current standards," radiation oncologist Kent Wallner, the VA expert who re-treated Armstrong, wrote in an Oct. 20, 2008, letter.

"The resulting complicated situation leaves him at considerable uncertainty regarding his

chance for a cure," Wallner wrote. "He is also . . . at higher than usual risk for a severe urinary or bowel complications due primarily to excess radiation."

Like Kao, Wallner inserted needles loaded with radioactive seeds into Armstrong's prostate while watching ultrasound images of the organ. But Wallner was so exacting that after placing 40 seeds in Armstrong's prostate, the doctor gauged the radiation dosage, then added four more rice-grain-sized particles.

"We elected to add four more seeds to try to bring it up closer to 100" percent, Wallner wrote in his operative note.

For Armstrong, the aftershocks of his original care at the Philadelphia VA added to the fallout of fighting in Vietnam - namely, posttraumatic stress syndrome.

"My girlfriend left me because of [erectile dysfunction]," he said during an interview in his lawyer Michael Barrett's Center City office. "I am just learning to be alone."

He also lives in fear the cancer will return, and of the tiny nuclear war inside him.

"I feel things in my body and think the worst," he wrote on the claim form he filed with the VA last summer. "I really don't know when something is going to happen. I can't get past it. I get depressed a lot."

Contact staff writer Marie McCullough at 215-854-2720 or mmccullough@phillynews.com